

REMARKS

Claims 40-70 are pending in the present application. Claims 53, 63 and 66 have been amended to refer to the terms systolic and diastolic blood pressure as requested by the Examiner. Page 11, lines 2 and 3, provide support for the ratio of (a)/(b) in food claim 46. Support for supplemented foods is found in the specification at page 11, lines 20-21 and page 12, lines 4-5. Dependent claims 47-52 have been revised to more clearly encompass supplemented foods. Accordingly, the Applicants do not believe that any new matter has been added.

The Applicants thank Examiner Hawes and Kishore for the courtesies extended during the interview on May 4, 2006. The Examiners were concerned that the food claims may read on unsupplemented food products containing naturally high levels of components (a) and (b) and suggested that the food claims be cancelled or directed to foods containing specific amounts or ratios of caffeic, ferulic or chlorogenic acid.

Rejection—35 U.S.C. §112, second paragraph

Claims 54, 55, 57, 58, 64, 65, 67 and 68 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. This rejection is moot in view of the amendments above.

Rejection/Provisional Rejections--Double Patenting

Claims 40-70 were rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,310,100 B1; or over claims 1-6 of copending Application No. 11/209,672.

The Applicants respectfully traverse the rejection over the claims of U.S. Patent 6,310,100, because these claims require a glyceride composition and do not require caffeic

and/or chlorogenic acid, as do the present claims. Thus, the present claims are patentably distinct from the claims of this prior patent.

With respect to the provisional rejection, the Applicants understand that upon an indication of allowability for the pending claims, the Applicants understand that the provisional double patenting rejection will be withdrawn, provided the claims in the copending application have not been allowed, MPEP 804(I)(B).

Rejection—35 U.S.C. §103

Claims 46-52 and 56-65 were rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham, *Fd. Chem. Toxic.* 34:15-20 (XP-001148404), in view of Hsu, U.S. Patent No. 5,958,417, and further in view of Ghai et al., U.S. Patent 5,955,269.

This rejection is moot in view of the incorporation of the limitation limiting the ratio of compounds (a)/(b) to 0.01 to 50 into independent Claim 46 from which the other claims depend and in view of the revised claim language from which unsupplemented foods have been excluded.

The cited prior art does not disclose or suggest foods supplemented with (a) isolated ferulic acid or ferulic acid esters + (b) isolated caffeic acid and/or chlorogenic acid or salts thereof where the ratio of (a) to (b) ranges from 0.01 to 50. The Examiner's expressed a concern in the recent interview that a food naturally containing a low level of (a) and (b) supplemented with (a) and (b), might be the same as a natural food naturally containing high amounts (a) and (b). That is, that the word "supplemented" was a product-by-process limitation that might not distinguish such products. To address this concern, Claim 46 now explicitly excludes unsupplemented foods.

Moreover, the limitation “supplemented” does distinguish the supplemented foods from unsupplemented foods. A natural food containing low levels of (a) and (b) would contain low levels of other natural compounds in the biochemical pathways that produce compounds (a) and (b) and low levels of other compounds produced using (a) and (b) as biochemical substrates. Similarly, a natural food containing high levels of (a) and (b) would contain high levels of natural precursors of (and products produced using) compounds (a) and (b). Even if a natural unsupplemented food product contained similar amounts of (a) and (b), it would not be expected to contain similar amounts of these other natural precursors or products of (a) and (b). Claim 46 explicitly requires supplementation with isolated or purified (a) and (b). Such isolated or purified (a) and (b) would not contain the natural precursors of (a) and (b) or products produced using (a) and (b) as substrates. Thus, supplementation of a food with isolated or purified ferulic acid and caffeic/cholorogenic acid, would produce a distinct supplemented food product not suggested by the prior art.

Along these lines, the Applicants reiterate their earlier arguments:

The cited prior art does not render the present invention obvious, because it does not disclose or suggest the composition or methods of the present invention which consists of isolated or purified ferulic acid in combination with isolated or purified chlorogenic and/or caffeic acid (and a carrier or excipient) in an amount sufficient to lower blood pressure or prevent a rise in blood pressure.

Abraham, Table 1, page 16, refers to oral pretreatment of Swiss albino mice with a combination of chlorogenic acid, caffeic acid, ellagic acid and ferulic acid and is concerned with the potential antioxidant, anti-genotoxic and anti-cancer properties of this composition. Unlike the claimed compositions, the composition (Code D) of Abraham also contains isolated ellagaic acid as an essential component. Abraham does not disclose a composition

consisting essentially of ferulic acid and chlorogenic acid or caffeic acid which lowers blood pressure.

Moreover, Abraham does not disclose the food products of Claims 46-52 which have been supplemented with ferulic acid and chlorogenic and/or caffeic acid, nor the methods for treating hypertension or for reducing blood pressure of Claims 53-68.

Hsu was cited as disclosing the functional activity of a herb, *Crataegus* (hawthorn), on hypertension (Fig. 1). While Hsu indicates that *Crataegus* contains various active principles, including ferulic, chlorogenic and caffeic acid (col. 2, lines 55-64), it does not indicate which of the many components of this herb are effective to treat hypertension, nor suggest that isolated ferulic acid in combination with isolated chlorogenic acid and/or caffeic acid would exert these effects. Thus, Hsu provides no suggestion or reasonable expectation of success for the present invention which employs isolated ferulic, chlorogenic and caffeic acids to reduce high blood pressure.

Ghai, col. 25, lines 1-3. col. 23, lines 43-50 and col. 27, lines 19-25, was cited as teaching nutraceutical compositions and fortification of foods with nutraceutical ingredients. Col. 23, lines 43-50 (Table 1) refer to various examples of food substances that may be employed as nutraceuticals. These foods include coffee, soybeans, and fruits which contain phenolic acids such as caffeic acid, chlorogenic acid, ferulic acid, and rosmarinic acid. However, like Hsu, Ghai provides no suggestion or reasonable expectation that isolated ferulic acid in combination with isolated chlorogenic and/or isolated caffeic acid would reduce blood pressure or suggest that these isolated acids be added to foods. Accordingly, the Applicants respectfully submit that this rejection should be withdrawn.

CONCLUSION

In view of the amendments and remarks above, the Applicants respectfully submit that the present application is now in condition for allowance. Early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon

A handwritten signature in black ink, appearing to read "Thomas Cunningham", written in a cursive style.

Thomas M. Cunningham, Ph.D.
Registration No. 45,394

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413-2220